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The National Professional Society of Pharmacists

CDER Stakeholders Meeting

Statement of American Pharmaceutical Association (APhA)
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August 17, 1998

Good morning, and thank you for this opportunity to provide ideas regarding priorities for the Center for Drug Evaluation and Research. I am John A. Gans, PharmD, Executive Vice President of the American Pharmaceutical Association, the national professional society of pharmacists. Speaking for the entire pharmacy profession is my unique privilege and responsibility, and on behalf of America's 190,000 pharmacists, please accept our thanks for continuing CDER's policy of openness and frank exchange of views with the health professions.

I will briefly address several key priorities this morning, and would be pleased to speak with you about these ideas at the appropriate time.

Need for a new classification scheme for prescription pharmaceuticals. All of us are aware of the steadily mounting evidence of morbidity and mortality attributable to underuse and misuse of prescription pharmaceuticals. This evidence has recently spilled over from its historical confinement in the pages of medical journals to play out in the lay media. The media, with the public not far behind, are demanding more accountability of manufacturers, physicians, and pharmacists.

Part of the problem is the fact that health professionals are being pushed by economic pressures into spending less time with each patient. In addition, the now ubiquitous use of formularies puts prescribers in particular in a position of being pressed to approve the use of drug products with which they have less familiarity than the originally prescribed product. These marketplace trends make it difficult for prescribers and pharmacists alike to remain alert to the risks of every drug they prescribe and dispense.

CDER could help this situation considerably by creating new classification scheme for prescription drugs, under which higher risk products would be identified as belonging to a category of drugs which demand special attention from clinicians and patients. This new risk stratification schedule would be analogous to the schedules defined in the Controlled Substances Act. Health professionals would know that a drug in the high risk category bears special or unusual risks that require close monitoring.

Drugs in the highest risk category might all be subject to a special distribution mechanism, such as that recently approved for thalidomide. In addition, "narrow therapeutic range" drugs might be placed in a higher risk category to higher risk products, based on FDA's

conclusion that the agency believes that such drugs require closer professional monitoring than other drug products. This would help prescribers and pharmacists know which drugs FDA believes are deserving of this attention.

Drug Advertising and Marketing. FDA has several initiatives underway in this high priority area. I will speak to three: (1) Sampling, (2) Direct to Consumer Advertising, (3) Distribution of Peer Reviewed Articles on Unapproved Uses, and (4) FDA's Draft Guidance on marketing by health care organizations such as PBMs on behalf of manufacturers.

Sampling. The distribution of costly drug product samples to prescribers is an archaic method of inducing sales of pharmaceuticals that undermines the few existing safeguards in today's drug distribution system. It deprives the patient of pharmacist counseling, which has been thought sufficiently important to patient health and safety as to warrant a statutory mandate by the United States Congress and over 40 State legislatures. It cheats the patient of even the basic written drug information they would receive at a pharmacy, perpetuating a problem which the Center had sought to address through its "Medguide" proposal. It adds costly packaging and record keeping responsibilities to drug distribution, with no corresponding benefit. CDER should seek the authority to ban the practice of distributing samples.

To facilitate the use of "starter" doses of medications for the purpose of determining the patient's compatibility with a given regimen, FDA should permit the use of numbered manufacturer vouchers which can be presented to the pharmacist along with the prescription for whatever supply is deemed necessary by the prescriber. The voucher or its unique number would be submitted by the pharmacist with each claim, to be subsequently redeemed by the payor with the issuing manufacturer.

Direct to Consumer Advertising. The cornerstone of the FDA's DTC policy is the physician's ability and willingness to decline to prescribe a product if and when a consumer requests a prescription that may not be appropriate. Yet, the literature is replete with evidence that physicians do not receive a comprehensive education in pharmacotherapy in medical school. Physicians are taught to focus on a relatively small number of products with which they have become familiar with side effects, dosing and other considerations. This is important because Direct to Consumer advertising, like the constantly changing demands of formulary systems, has the effect of asking physicians to prescribe outside of that zone of familiarity and safety.

This is worthy of your attention because there is evidence that DTC ads work. APhA conducted a national survey of consumers just prior to the initiation of FDA's trial period of relaxed regulations for direct to consumer advertising. We believe this will provide CDER with baseline data from which to analyze the impact of the new trial policy. Perhaps the two most important results in that survey indicate that –

(1) The impact of DTC ads may be felt disproportionately by those targeted: People with the disease state treated by product in DTC ad are more likely to report seeing a DTC ad for such a product. For example:

7% of all consumers report seeing DTC ad for dyslipidemia product, but 22% of consumers who report suffering from dyslipidemia say they've seen such an ad.

Similarly, 6% of all consumers report seeing DTC ad for hypertension product, but 18% of consumers who report suffering from hypertension say they've seen an ad.

These findings are important because they suggest the chronically ill -- those most reliant on pharmacotherapy -- are likely to be most affected by DTC ads.

(2) The second major discovery of the APhA/*Prevention* survey is that if one projects our survey respondents to U.S. population, about 35 million Americans spoke with their doctor about a product "as a direct consequence of DTC advertising." About 10.2 million asked for a prescription of product for which they saw DTC ad. At the end of the day, about 7.5 million received a prescription for the product they asked for. These data are cumulative, since DTC advertising began.

Given the these ads may influence prescribing, CDER should work with the professions to develop a methodology for measuring whether adverse events or other problems are more frequent where prescribing has resulted from DTC advertising.

Information about Unapproved Uses of Pharmaceuticals. Under FDAMA, manufacturers can distribute peer reviewed articles about unapproved uses to prescribers. This is a meaningful reform that should enhance the knowledge base of prescribers when it comes to off label uses of approved drugs. CDER should submit a formal proposal to the Administration for delivery to Congress that would permit such information to be shared with pharmacists, as well. This would help pharmacists to know more about the uses physicians for which are prescribing medications. But the policy change that would help the most is for State and Federal Government to insist that the intended use be written on every prescription. Counseling is very different for a patient getting propranolol for headaches rather than for a cardiovascular condition. Please note that the intended use is not the same as the diagnosis, which can remain confidential.

Draft Guidance on Marketing by Health Care Organizations on Behalf of Manufacturers. APhA agrees with FDA that current law permits the agency to regulate false or misleading information when it is promulgated by organizations other than manufacturers, provided that FDA can demonstrate that these organizations are acting on behalf of the manufacturer. FDA's draft Guidance to clarify this common sense rule as Agency policy is a welcome initiative.

One modification to the Guidance is needed. APhA believes that the same test to determine whether a PBM or other organization has acted on behalf of a manufacturer should be applied to subsidiaries and to entities operating under contract with a manufacturer.

Some will tell the Agency that there is no need for FDA action in this area, because PBMs cannot stay in business if they slavishly move their parent company's products at a higher cost to their client. These market pressures to reduce drug product prices do exist. However, economic pressures to use the least costly drug product will do nothing to offset the incentive a PBM may have to mischaracterize two products as equally effective or equally safe for all patients, and may even encourage such mischaracterizations.

PBMs seldom bear any financial risk for the health consequences of inappropriate drug therapy. If a PBM develops a formulary that induces prescribers to utilize one product out of several in a given therapeutic niche, and provides no rapid and fair opportunity for appealing that decision, that PBM is marketing that product as equivalent for all patients. Such assumptions of equivalence are rarely supported with documentation from controlled clinical trials, and cannot safely be imposed on an entire population of health plan enrollees. In any large population of individuals, there are those who may experience clinically significant differences in pharmacodynamic response to the same product due to racial or other physiological attributes. These variations mean that formularies must be administered in a way that permits adjustment for individual patients upon the request of the prescriber. There is little question that formularies have contributed significantly to cost savings and rational prescribing in health care settings such as hospitals. It is essential for CDER to ensure PBMs and other health care organizations do not convert formularies into an inflexible tool of drug product marketing that benefits a manufacturer but not patients.

Postmarket Surveillance. There are two problems in this important function of the Center. First, FDA does not receive a sufficient number of adverse drug reports, if we are to believe published reports regarding the amount of morbidity and mortality associated with drug use. The Agency needs to work with prescribers and pharmacists, to promote swift reporting of all adverse events to FDA.

Second, passive reporting is insufficient as a strategy to identify adverse effects and problems with appropriate prescribing and use of pharmaceuticals. FDA's current system for identifying hitherto unknown adverse effects of prescription drugs suffers from a lack of resources to analyze and respond to reports received by the Agency. Pharmacists have demonstrated that their active participation in Phase IV studies produces valuable data about the safety and effectiveness of approved products. APhA would like to work with the Center to use this promising mechanism more often when products are approved.

Recalls. Pharmacists often have difficulty receiving accurate and timely information about drug product recalls, even class 1 recalls. CDER should take steps to encourage manufacturers to utilize the latest in notification technologies, such as telephonic notification followed up by overnight mail notification. APhA would be pleased to work with the Center on such an initiative.